IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

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12-30-00

In re PATENT APPLICATION of

SHIFF et al.

Group Art Unit: 2856

Appln. No.: 09/006,999

Examiner: M. Cygan

Filed: January 14, 1998

Title: APPARATUS FOR THE SEPARATION OF CYSTIC PARASITE FORMS FROM WATER

* * * * *

December 21, 2000

APPEAL BRIEF

Hon. Commissioner of Patents
and Trademarks
Washington, D C. 20231

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Sir:

Appellants submit herewith their Appeal brief in triplicate, pursuant to 37 C.F.R. §1.192.

REAL PARTIES IN INTEREST

The real party in interest is Johns Hopkins University, by virtue of assignment from the Applicants.

RELATED APPEALS AND INTERFERENCES

There are no other appeals or interferences known to the Appellants or the Appellants' legal representative, or the assignee, that will directly affect or will be directly affected by or have bearing on the Board's decision in this appeal.

STATUS OF CLAIMS:

Claims 1, 4, 6-8 and 10-12 have been finally rejected by the Examiner and are at issue in this appeal. The claims on

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appeal are set forth in the Appendix to this brief.

STATUS OF AMENDMENTS:

No responses have been submitted subsequent to the Examiner's final rejection of June 22, 2000.

SUMMARY OF THE INVENTION:

The invention is a continuous flow centrifuge apparatus, with an improvement comprising the addition of a filtration column of particulate material, and a method for concentrating or isolating a microorganism from an aqueous suspension using the apparatus (described in the specification at page 5, line 9 to page 6, line 14). Filtration within a tube of water under the forces of centrifugation is used to separate small parasite products (of 4-10 microns in diameter) from raw water. The improved apparatus can perform filtration of 20 liters or more of water already containing particulates and colloidal matter per sample, and is efficient in removing *Cryptosporidium* oocytes for purification or testing.

ISSUE:

Whether the Examiner's rejection of claims 1, 4, 6-8 and 10-12 under 35 U.S.C. § 103(a), as being unpatentable over Borchardt et al. (U.S. Pat. No. 5,846,439) in view of Leu (U.S. Pat. No. 5,866,071), should be reversed.

GROUPING OF THE CLAIMS:

The claims should be considered separately for the purposes of patentability for the reasons set forth below.

THE EXAMINER'S POSITION:

It is the Examiner's position that the combination of Borchardt et al. with Leu results in the invention as claimed in claims 1, 4, 6-8 and 10-12, and that the claims are therefore obvious in view of the cited art.

ARGUMENT:

The Examiner stated that with respect to claim 1, Borchardt teaches the claimed invention except for the use of a particulate filtrate column. Appellants respectfully disagree. Borchardt teaches the use of a continuous separation channel centrifuge, as depicted in Figure 1 of U.S. Pat. No. 5,846,439. The centrifuge used in the methods according to the present invention is completely different, as

shown in Figure 1 of the present application. In the method taught by Borchardt, collected parasites are retained in the channel labelled "12" in Figure 1. In Appellants' invention, parasites are collected in replaceable sample tubes. It is respectfully submitted that a filtration column of particulate material, as employed in the present invention, cannot be added to a channel as taught by Borchardt. Furthermore, in the method disclosed by Borchardt, the collected material must be removed from the separation channel before a subsequent sample can be processed. In Appellants' claimed method, the sample collection tubes need merely be replaced.

Appellants also respectfully submit that the centrifuge apparatus used by Borchardt is far more complex that that of the present invention, and will not be operable for the purposes of the present invention. Any apparatus used for these purposes must perform with natural water with various quantities of sediment. A delicate piece of apparatus designed for medical work, as used by Borchardt, that was designed to centrifuge a few liters of blood, cannot handle quantities up to 20-30 liters of water.

Finally, it is respectfully submitted that the Borchardt patent "teaches away" from the present invention. For example, at column 2, lines 28-29, it is stated that "the sand column system was judged inadequate for monitoring because of the poor retention of oocysts…".

The Leu patent does not remedy the deficiency of the Borchardt patent to suggest the present invention. First, there is no suggestion in either Borchardt or Leu that would motivate a person skilled in the art to combine the two documents. The Borchardt patent is directed to use of a continuous separation channel centrifuge, whereas the Leu patent is directed to a centrifuge tube to be used for separation after density gradient centrifugation. These two processes are inherently different. Furthermore, there does not appear to be any way that the centrifuge tube of Leu can be combined with Borchardt to yield the present invention. In addition, the centrifuge tube of Leu is designed for removal of gradients following density gradient separation, and not for operation during the centrifugation process itself. It is respectfully submitted that even were the teachings of these two patents able to be combined, it would not result in the present invention. Finally, as noted above, Borchardt teaches away from the use of a sand column system, and makes no mention of glass beads. Thus, the suggestion to use the required element of a filtration column of particulate material is missing from the teachings of these documents. For all of these reasons, it is respectfully submitted that the invention claimed in claim 1 is not obvious in view of Borchardt and Leu. For all of the above reasons, reversal of the Examiner's 35 USC § 103 rejection of claim 1 is

respectfully requested.

With respect to claims 4 and 12, it is the Examiner's position that Borchardt in view of Leu teaches the claimed invention as stated above except for the use of glass or sand particulate material, and that Borchardt discloses that it is known in the art to use sand columns to filter oocysts from water in flow systems. According to the Examiner's position, it would be obvious to use sand columns in the centrifuge of Borchardt in replacement of the media of Leu, as sand columns are known to filter oocysts.

Appellants disagree. As discussed above, Borchardt teaches away from the use of sand columns, and makes no mention of glass beads. Accordingly, it is submitted that the combination of Borchardt with Leu as suggested by the Examiner would not be obvious to a person of skill in the art, and would not result in the invention of claims 4 and 12. For these reasons, and for the reasons presented earlier for claim 1, reversal of the Examiner's 35 USC § 103 rejection of claims 4 and 12 is respectfully requested.

With respect to method claims 6-8, it is the Examiner's position that Borchardt teaches that it is known in the art to perform microorganism, cryptosporidium in particular, concentration in a fluid stream of a continuous flow centrifuge. However, the combination of Borchardt and Leu fails to disclose an apparatus that is capable of

concentrating microorganisms from large volumes of fluid, as is Appellants' claimed apparatus. Any apparatus used for these purposes must perform with natural water with various quantities of sediment. A delicate piece of apparatus designed for medical work, as used by Borchardt, that was designed to centrifuge a few liters of blood, cannot handle quantities up to 20-30 liters of water. For this reason, it is respectfully submitted that any apparatus resulting from the combination of Borchardt with Leu would not be able to carry out the method of the invention as claimed in claims 6-8. Accordingly, it is respectfully requested that the 35 USC§ 103(a) rejection of claims 6-8 be reversed.

With respect to claims 11-12, it is the Examiner's position that the combination of Borchardt with Leu yields the claimed invention except for the claimed size ranges for the beads or sand, which are considered to be a matter of routine experimentation. Appellants agree that <u>if</u> Borchardt combined with Leu resulted in the present invention, as broadly claimed, the size of the beads and sand might be considered a matter of routine experimentation. However, Appellants submit that Borchardt combined with Leu does <u>not</u> result in the present invention, as broadly claimed. Therefore, no amount of routine experimentation would result in the invention as claimed in claims 10-11. For this reason, it is respectfully requested that the rejection of claims 10-11 under 35 USC §

103(a) be reversed.

CONCLUSION:

In summary, Appellants submit that

1. There is no motivation for a person of skill in the art to combine Borchardt and Leu patents;

2. Even were such a combination to be made, it would not result in the present invention; and

3. The primary reference, Borchardt, teaches away from the present invention.

For these reasons, it is respectfully requested that the 35 USC § 103(a) rejection of claims be reversed and the application be allowed to issue.

Respectfully submitted,

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Appendix

1. In a continuous flow centrifuge apparatus, the improvement comprising the addition of a filtration column of particulate material.

4. The apparatus of claim 1 in which said particulate material is graded glass beads or sand.

6. A method for concentrating or isolating a microorganism from an aqueous suspension, said method comprising centrifuging said solution using the apparatus of claim 1.

7. In a method for concentrating, isolating or detecting a microorganism using a continuous flow centrifuge, the improvement comprising using a filtration column of particulate material in the fluid stream of the centrifuge.

8. The method of claim 7 in which the microorganism is a cyst of cryptosporidium or giardia.

10. In a continuous flow centrifuge apparatus, the improvement comprising the addition of a filtration column of particulate material, wherein said particulate material is selected from the group consisting of graded glass beads of

120-50 μm and fine sand of 200-50 μm and the column is at least about 7 cm in height.

11. A continuous flow centrifuge apparatus which is adapted to include a filtration column of particulate material having a size range of 120-50 μm.

12. In a method for concentrating, isolating or detecting a cyst of cryptosporidium or giardia using a continuous flow centrifuge, the improvement comprising using a filtration column of graded glass beads or sand in the fluid stream of the centrifuge.